

Application No.: 10/078805

Case No.: 51737US019

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1-41. (Cancelled)

42. (Currently amended) A sustained release medicinal aerosol formulation comprising:

- (a) a propellant;
- (b) A therapeutically effective amount of a drug; and
- (c) a sufficient amount of a biocompatible polymer substantially completely dissolved in the formulation so as to provide for sustained release of the drug;

wherein the sustained release formulation results in discrete, nonfilm forming particles upon delivery, and

wherein the formulation is contained in a metered dose inhaler for oral and/or nasal inhalation, and
wherein the biocompatible polymer comprises at least one chain of units of the formula

-[X-R¹-C(O)]- wherein:

- (a) each R¹ is an independently selected organic group that links the X group to the carbonyl group; and
- (b) each X is independently oxygen, sulfur, or catenary nitrogen.

43. (Cancelled).

44. (Currently amended). The sustained release formulation of claim [423], wherein the biocompatible polymer is present in an amount of greater than 1 part by weight based on 100 parts of the formulation.

45. (Withdrawn)

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46. (Original) The sustained release formulation of claim 42 wherein the drug is substantially completely dissolved in the formulation.

47. (Original) The sustained release formulation of claim 42 wherein the biocompatible polymer is present in an amount such that the period of therapeutic activity of the drug is increased by a factor of at least about 1.5 relative to the period of activity of the same formulation with respect to the propellant and drug but without the biocompatible polymer.

48. (Original) The sustained release formulation of claim 42 wherein the biocompatible polymer is present in an amount such that the period of therapeutic activity of the drug is increased by at least about 30 minutes relative to the period of activity of the same formulation with respect to the propellant and drug but without the biocompatible polymer.

49. (Original) The sustained release formulation of claim 42 wherein the biocompatible polymer is present in an amount of no greater than about 25 parts by weight based on 100 parts of the formulation.

50. (Original) The sustained release formulation of claim 46 wherein the biocompatible polymer is present in an amount ranging from 0.01 to 10 parts by weight based on 100 parts of the formulation.

51. (Original) The sustained release formulation of claim 42 wherein the biocompatible polymer contains amide groups, ester groups, or mixtures thereof.

52. (Original) The sustained release formulation of claim 42 wherein the biocompatible polymer has a number-average molecular weight of no greater than about 5000.

53. (Original) The sustained release formulation of claim 42 wherein the biocompatible polymer is a condensation polymer.

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54. (Canceled)

55. (Currently amended) The sustained release formulation of claim [54-42] wherein each X is independently oxygen or catenary nitrogen.

56. (Currently amended) The sustained release formulation of claim [54-42] wherein each R¹ is a straight chain, branched chain, or cyclic organic group containing 1-6 carbon atoms optionally containing carbonyl groups, oxygen atoms, thiol groups, or catenary nitrogen atoms.

57. (Currently amended) The sustained release formulation of claim [54-42] wherein the biocompatible polymer chain comprises units derived from one or more precursor hydroxyacids.

58. (Currently amended) The sustained release formulation of claim [54-42] wherein the biocompatible polymer chain comprises units derived from precursors selected from the group consisting of glycolic acid, trimethylene carbonate, hydroxybutyric acids, p-dioxanone, and lactic acids.

59. (Currently amended) The sustained release formulation of claim [54-42] wherein the biocompatible polymer chain comprises units derived from precursors selected from the group consisting of alpha-hydroxycarboxylic acids and beta-hydroxycarboxylic acids.

60. (Original) The sustained release formulation of claim 59 wherein the biocompatible polymer chain comprises units derived from alpha-hydroxycarboxylic acid precursors.

61. (Currently amended) The sustained release formulation of claim [54-42] wherein the biocompatible polymer has an average chain length of no greater than about 70 of said units.

62. (Original) The sustained release formulation of claim 61 wherein the biocompatible polymer has an average chain length of no greater than about 25 of said units.

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63. (Original) The sustained release formulation of claim 62 wherein the biocompatible polymer has an average chain length of no greater than about 16 of said units.

64. (Original) The sustained release formulation of claim 63 wherein the biocompatible polymer has an average chain length of no greater than about 11 of said units.

65. (Original) The sustained release formulation of claim 61 wherein the biocompatible polymer has an average chain length of at least about 5 of said units.

66. (Original) The sustained release formulation of claim 65 wherein the biocompatible polymer has an average chain length of at least about 8 of said units.

67. (Currently amended) The sustained release formulation of claim [~~54-42~~] wherein the biocompatible polymer is biodegradable.

68. (Original) The sustained release formulation of claim 67 wherein the biodegradable polymer has a biological half-life of less than about 10 days.

69. (Currently amended) The sustained release formulation of claim [~~54-42~~] wherein the biocompatible polymer has a number-average molecular weight of no greater than about 5000.

70. (Original) The sustained release formulation of claim 69 wherein the biocompatible polymer has a number-average molecular weight of no greater than about 1800.

71. (Original) The sustained release formulation of claim 70 wherein the biocompatible polymer has a number-average molecular weight of no greater than about 1200.

72. (Original) The sustained release formulation of claim 69 wherein the biocompatible polymer has a polydispersity of less than about 1.4.

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73. (Original) The sustained release formulation of claim 70 wherein the biocompatible polymer has a polydispersity of less than about 1.2.

74. (Currently amended) The sustained release formulation of claim [54-42] further comprising a cosolvent.

75. (Original) The sustained release medicinal formulation of claim 74 wherein the cosolvent is selected from the group consisting of ethanol, isopropanol, acetone, ethyl lactate, dimethyl ether, tetrahydrofuran, and ethyl acetate.

76. (Currently amended) The sustained release formulation of claim [54-42] wherein the propellant comprises a chlorofluorocarbon, a hydrochlorofluorocarbon, a hydrofluorocarbon, carbon dioxide, dimethyl ether, butane, propane, or a mixture thereof.

77. (Currently amended) The sustained release formulation of claim [54-42] wherein the drug is selected from the group consisting of antiallergics, analgesics, bronchodilators, antihistamines, antiviral agents, antibiotics, anti-inflammatories, immunomodulators, peptides, and steroids.

78. (Currently amended) The sustained release formulation of claim [54-42] wherein the drug is selected from the group consisting of adrenaline, albuterol, atropine, beclomethasone dipropionate, budesonide, butixocort propionate, clemastine, cromolyn, epinephrine, ephedrine, fentanyl, flunisolide, fluticasone, formoterol, ipratropium bromide, isoproterenol, lidocaine, morphine, nedocromil, pentamidine isoethionate, pirbuterol, prednisolone, salmeterol, terbutaline, tetracycline, 4-amino- $\alpha,\alpha,2$ -trimethyl-1H-imidazo[4,5-c]quinoline-1-ethanol, 2,5-diethyl-10-oxo-1,2,4-triazolo[1,5-c]pyrimido[5,4-b][1,4]thiazine, 1-(1-ethylpropyl)-1-hydroxy-3-phenylurea, and pharmaceutically acceptable salts and solvates thereof, and mixtures thereof.

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79. (Currently amended) The sustained release formulation of claim [54-42] wherein the biocompatible polymer is present in at least about a 4:1 ratio by weight of biocompatible polymer to drug, and the drug is present as a micronized suspension.

80. (Original) The sustained release formulation of claim 79 wherein the biocompatible polymer is present in at least about a 8:1 ratio by weight of biocompatible polymer to drug, and the drug is present as a micronized suspension.

81. (Currently amended) The sustained release formulation of claim [54-42] wherein the biocompatible polymer is present in an amount of from about 1:1 to about 100:1 ratio by weight of biocompatible polymer to drug, and the drug is substantially completely dissolved in the formulation.

82. (Original) The sustained release formulation of claim 81 wherein the biocompatible polymer is present in an amount of from about 2:1 to about 30:1 ratio by weight of biocompatible polymer to drug, and the drug is substantially completely dissolved in the formulation.

83. (Currently amended) The sustained release formulation of claim [54-42] wherein the period of therapeutic activity is extended by at least about 6 hours.

84. (Currently amended) The sustained release formulation of claim [54-42] wherein the biocompatible polymer has a molecular weight polydispersity of no greater than about 1.8.

85. (Currently amended) The sustained release formulation of claim [54-42] wherein the biocompatible polymer has a molecular weight polydispersity of no greater than about 1.4.

86. (Currently amended) The sustained release formulation of claim [54-42] wherein the biocompatible polymer has a molecular weight polydispersity of no greater than about 1.2.

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87. (Currently amended) The sustained release formulation of claim [54-42] in an aerosol canister |
equipped with a metered dose valve.